Louisiana Medicaid
Fosdenopterin (Nulibry™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for fosdenopterin (Nulibry™).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- **One** of the following applies and is **stated on the request**:
    - The recipient has a diagnosis of Molybdenum Cofactor Deficiency Type A (MoCD Type A) confirmed by genetic testing which demonstrates a mutation in the *MOCS1* gene; **OR**
    - The recipient has biochemical features suggestive of MoCD Type A (i.e., elevated sulfites in urine, low serum uric acid, elevated urinary xanthine and hypoxanthine) and will be treated presumptively while awaiting genetic confirmation (in this situation, genetic confirmation must be submitted for reauthorization); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a geneticist or neurologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial authorization approval: 3 months

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy; **AND**
- If the recipient was treated presumptively with Nulibry™ while awaiting genetic testing results, the prescriber **states on the request** that genetic testing confirms the diagnosis of MoCD Type A.

Duration of reauthorization approval: 12 months

References

Mechler, K., Mountford, W., Hoffmann, G. *et al.* Ultra-orphan diseases: a quantitative analysis of the natural history of molybdenum cofactor deficiency. *Genet Med* 17, 965–970 (2015). https://doi.org/10.1038/gim.2015.12

Nulibry (fosdenopterin) [package insert]. Boston, MA: Origin Biosciences, Inc; February 2021. https://www.nulibry.com/pdfs/nulibry-prescribing-information-v2.pdf

Revision / Date	Implementation Date
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